a) contacting the antibody produced by the method of claim 31 with said sample, and

b) detecting specific binding of said antibody to said sample, wherein the presence of specific binding indicates the presence of a polypeptide having the amino acid sequence of either SEQ ID NO:1 or SEQ ID NO:2 in said sample.

REMARKS

Claims 1, 2, 14-18, and 21-27 are pending.

Claims 1, 2, 21, 22, and 27 are currently under consideration.

New claims 28-32 are added.

Applicants thank the Examiner for considering the arguments submitted in the communication mailed May 22, 2000, for entering the amendments to claims 1 and 2, and for withdrawing several of the rejections made in the Office Action mailed February 22, 2000. Applicants reserve the right to prosecute the non-elected claims in subsequent divisional applications.

Justification for the amendments is as follows. The amendments to the specification serve to correct inadvertent typographical errors, and thus further clarify the subject matter which Applicants consider to be the invention. The amendments to claim 1, and the addition of new claims 28-32, serve to further clarify the subject matter which Applicants consider to be the invention. Support for new claim 30 is found in the specification at, for example, p. 49, lines 30-33 and p. 50, lines 1-3. Support for new claim 31 is found in the specification at, for example, p. 49, lines 1-16. Support for new claim 32 is found in the specification at, for example, p. 34, lines 2-10. No new matter is added by any of these amendments.

I. Rejections under 35 U.S.C. § 102(b)

The rejection of claim 1 under 35 U.S.C. § 102(b) was maintained. Fragments of SEQ ID NO:2 are allegedly anticipated by either Yu et al. or Andersson et al. Applicants note that paragraph 10 of the instant Office Action states that fragments of SEQ ID NO:1 are anticipated by these references while, in the previous Office Action mailed February 22, 2000, it is stated that fragments of SEQ ID NO:2 are anticipated by these references. Based on the sequence

alignment data provided to the Applicants by the Examiner, Applicants submit that in fact SEQ ID NO:2 is the correct sequence in question, and that the statement in the instant Office Action was an inadvertent error.

Applicants have amended claim 1 such that it no longer recites fragments of SEQ ID NO:2. Applicants submit that claim 1, as amended, is not anticipated by either the Yu et al. or Andersson et al. references. Therefore, Applicants respectfully request that the Examiner withdraw this rejection of claim 1 under 35 U.S.C. § 102(b).

II. Rejections under 35 U.S.C. § 103(a)

The rejection of claim 27 under 35 U.S.C. § 103(a) was maintained. Fragments of SEQ ID NO:2 are allegedly obvious and unpatentable over Yu et al. and Andersson et al. in view of Harlow and Lane. Applicants have amended claim 1 such that it no longer recites fragments of SEQ ID NO:2. Since the composition of claim 27 is dependent on the polypeptides of claim 1, Applicants submit that claim 27 is not obvious based on Yu et al. and Andersson et al. in view of Harlow and Lane. Therefore, Applicants respectfully request that the Examiner withdraw this rejection of claim 27 under 35 U.S.C. § 103(a).

III. Rejections under 35 U.S.C. § 112, first paragraph

Claims 1, 2, 21, 22, and 27 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably provide enablement for a person of skill in the art to make and use the invention in a manner commensurate with the scope of the claims. Specifically, the specification allegedly does not reasonably provide enablement for the use of SEQ ID NO:1 or SEQ ID NO:2 in the treatment of neoplastic and reproductive disorders, or as diagnostic tools. Applicants respectfully traverse this rejection.

Applicants note that at least 72% of the tissue libraries in which PGAMP-1 was detected were cancerous or immortalized (specification, p. 14, lines 10-11), and that at least 76% of the tissue libraries in which PGAMP-2 was detected were cancerous or immortalized (specification, p. 15, lines 5-6). Applicants submit that because the expression of the claimed polypeptides are specific, to a statistically significant degree, to cancerous tissue, a person of skill in the art would know how to use these polypeptides for the identification of cancerous tissue. Although these

polypeptides are not expressed solely in cancerous tissue, they could still be used for indicating, with a reasonable chance of success, whether any particular tissue tested was cancerous. Such a utility for these polypeptides is asserted in the specification at, for example, p. 33, lines 26-33. Methods for the detection of the claimed polypeptides in biological samples is supported in the specification at, for example, p. 34, lines 2-10. Applicants submit that the use of the claimed polypeptides for determining whether a tissue sample is cancerous is fully enabled by the specification. Since one of skill in the art would know how to use the claimed invention to carry out this asserted utility, Applicants respectfully request that the Examiner withdraw this rejection of claims 1, 2, 21, 22, and 27 under 35 U.S.C. § 112, first paragraph.

IV. Rejections of claim 2 under 35 U.S.C. § 112, first paragraph

Claim 2 was rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably provide enablement for a person of skill in the art to make and use the invention in a manner commensurate with the scope of the claims. Specifically, the specification allegedly does not reasonably provide enablement for polypeptides having at least 90% sequence identity to SEQ ID NO:1 or SEQ ID NO:2.

Applicants note that the polypeptide variants of claim 2 have the limitation of binding specifically to either an anti-PGAMP-1 antibody or an anti-PGAMP-2 antibody. The production of such antibodies is supported in the specification at, for example, p. 49, lines 1-16. The detection of specific binding between such antibodies and the claimed polypeptides is supported in the specification at, for example, p. 28, lines 7-13. It would be routine for a person of ordinary skill in the art to make any of the claimed polypeptide variants having at least 90% sequence identity to SEQ ID NO:1 or SEQ ID NO:2, and then to determine whether it specifically bound to either an anti-PGAMP-1 antibody or an anti-PGAMP-2 antibody. Applicants submit that polypeptide variants which, due to alternative splicing or post-translational modifications, would be significantly different, structurally and functionally, from the claimed polypeptides of SEQ ID NO:1 or SEQ ID NO:2, do not fall under the genus of claim 2, as such polypeptide variants would likely not demonstrate specific binding to anti-PGAMP-1 antibodies or anti-PGAMP-2 antibodies. Based on these arguments, Applicants submit that claim 2 is fully enabled by the specification, and therefore Applicants request that the Examiner withdraw this rejection of claim

2 under 35 U.S.C. § 112, first paragraph.

V. Utility rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claims 1, 2, 21, 22, and 27 were rejected under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by either a specific and substantial utility, or a well established utility. Claims 1, 2, 21, 22, and 27 were also rejected under 35 U.S.C. § 112, first paragraph, since if the claimed invention is not supported by either a specific and substantial utility, or a well established utility, one of skill in the art would not know how to use the claimed invention. Applicants respectfully traverse this rejection.

Applicants note that at least 72% of the tissue libraries in which PGAMP-1 was detected were cancerous or immortalized (specification, p. 14, lines 10-11), and that at least 76% of the tissue libraries in which PGAMP-2 was detected were cancerous or immortalized (specification, p. 15, lines 5-6). Applicants submit that because the expression of the claimed polypeptides are specific, to a statistically significant degree, to cancerous tissue, they have utility in the identification of cancerous tissue. Although these polypeptides are not expressed solely in cancerous tissue, they would still have utility in indicating, with a reasonable chance of success, whether any particular tissue tested was cancerous. Such a utility for these polypeptides is asserted in the specification at, for example, p. 33, lines 26-33. Methods for the detection of the claimed polypeptides in biological samples is supported in the specification at, for example, p. 34, lines 2-10. Applicants note that the statutory standard for the utility requirement does not require that a claimed invention have an asserted utility which is perfect in every regard, but that a person of ordinary skill in the art would **more likely than not** find that an asserted utility was credible. Applicants submit that using the claimed polypeptides to determine whether a tissue sample was cancerous is a credible, specific, and substantial utility, based on the very significant specificity of the expression of the polypeptides in cancerous and immortalized tissues. Applicants readily admit that such a utility is not foolproof, but no such diagnostic test is foolproof in any case. As Applicants have met the statutory requirements for utility of the claimed invention, Applicants respectfully request that the Examiner withdraw this rejection of claims 1, 2, 21, 22, and 27 under 35 U.S.C. § 101. Also, as one of skill in the art would know how to use the claimed invention to carry out this asserted utility, Applicants respectfully request

that the Examiner withdraw this rejection of claims 1, 2, 21, 22, and 27 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (650) 621-7542 or (650) 621-8581.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108. This form is enclosed in duplicate.**

Respectfully submitted,

INCYTE GENOMICS, INC.

Date: 11/15/2000

Terence P. Lo, Ph.D.
Limited Recognition (37 C.F.R. § 10.9(b)) attached
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